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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,049	03/16/2004	Dean L. Kamen	1062/E13	4610
2101	7590	09/07/2005	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			FASTOVSKY, LEONID M	
			ART UNIT	PAPER NUMBER
			3742	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/803,049	Applicant(s) KAMEN ET AL.	
	Examiner Leonid M. Fastovsky	Art Unit 3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 4-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 23-25 and 27-29 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20050321</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,464,667 of Kamen et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method for preparing an intravenous drug, comprising providing a disposable cassette having a liquid inlet, a vial receptacle, and a delivery chamber; attaching a supply of liquid to the liquid inlet, attaching the vial to the vial receptacle, introducing a volume of liquid into the vial, causing the liquid to flow between the vial and the chamber, and causing an additional volume of liquid to be mixed with the drug in the delivery chamber. However, Kamen does not claim two vials in the method. It would have been obvious to modify Kamen's invention to include two vials instead of one in order to easier mix different drugs in the cassette.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Pastrone et al (5,496,273).

Pastrone teaches a method for preparing an intravenous drug in a vial 8-10, the method comprising providing a cassette 30 that can inherently be disposed by disconnecting an inlet port 46 and an outlet port 66, a vial 2, 4, 6 with a receptacle and a delivery chamber 52, attaching a supply of liquid 14 to the liquid inlet 24, and causing the liquid to flow between the vial 8 and the chamber 62, and causing an additional volume of liquid to be mixed to dilute the drug in the delivery chamber 52.

As for claims 27-~~29~~, Pastrone teaches a mixing chamber 50 and a delivery chamber 52.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pastrone.

Pastrone discloses substantially the claimed invention including a secondary inlet port 47 which remains normally closed, but does not disclose a powdered drug delivery.

However, if desired, the port 47 can receive a second drug (col. 2, lines 50-61). It would have been obvious to one having ordinary skill in the art to modify Pastrone's invention to include a second port for delivery a powdered drug in order to meet requirements of the user.

Allowable Subject Matter

6. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments with respect to claims 1-3, 23-25 and 27-29 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonid M Fastovsky whose telephone number is 571-272-4778. The examiner can normally be reached on M-Th. 8.00 am -6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on 571-272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 3742



Leonid M Fastovsky

Examiner

Art Unit 3742

Imf

8/31/05



ROBIN O. EVANS

PRIMARY EXAMINER

9/2/05